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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) 022956-0217	
		Application Number 10/602,797-Conf. #1008	Filed June 24, 2003
		First Named Inventor Thomas C. May	
		Art Unit 3764	Examiner M. A. Brown
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <p><input type="checkbox"/> applicant /inventor. _____ Signature William C. Geary III/</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96) _____ Typed or printed name William C. Geary III</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number 31,359 _____</p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. _____ Telephone number (617) 439-2000</p> <p>Registration number if acting under 37 CFR 1.34. _____ November 22, 2006 Date</p> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p> <p><input type="checkbox"/> *Total of 1 forms are submitted.</p>			

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Dated: November 22, 2006

Signature: 
(William C. Geary, III)

Docket No.: 022956-0217
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Thomas May

Application No.: 10/602,797

Filed: June 24, 2003

For: **POROUS RESORBABLE GRAFT FIXATION PIN**

Confirmation No.: 1008

Art Unit: 3764

Examiner: Michael A. Brown

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Alexandria, VA 22313-1450

COMMENTS FOR PRE-APPEAL BRIEF REQUEST FOR REVIEW

Dear Sir:

These comments are being filed concurrently with a Notice of Appeal, and a Pre-Appeal Brief Request for Review.

A clean version of the *Pending Claims* is attached hereto.

REMARKS

Claims 1-30 are pending and stand rejected.

Claims 1-30 are rejected pursuant to 35 U.S.C. § 103(a) as being unpatentable over Dreyfuss (U.S. Pub. No. 2003/0065361) in view of Gogolewski *et al.* (U.S. Pat. No. 5,236,431), along with Sasso *et al.*, (U.S. 2004/0225292).

Independent Claim 25

Claim 25 is directed to a method for attaching a tissue graft to a bone. The Examiner rejects claim 25 on two grounds. First, the Examiner argues that the Dreyfuss and Gogolewski references teach the claimed method, except for injecting a treatment material into a tissue fixation device. The Examiner relies on Sasso to teach the injection of an active material in fixation device. (*See* Office Action dated February 7, 2006, pgs. 2-3). Second, the Examiner asserts that claim 25 does not positively recite the limitation of inserting a tissue graft into a bone tunnel, and argues that the prior art need only be capable of performing the method step. The Examiner maintains that a tissue graft could be inserted into the bone cavity created when the device taught by Dreyfuss is inserted into bone. (*See* Final Office Action dated July 25, 2006, pg. 4).

Applicant believes that the rejections of claim 25 are deficient because the Examiner fails to establish one or more of the essential elements needed for a *prima facie* obviousness rejection at least because the Examiner fails to establish that the prior art teaches all limitations recited in claim 25.

To begin with, none of the cited prior art references teaches or suggests the claimed steps of forming a bone tunnel into bone, positioning a tissue graft in the bone tunnel, and inserting a tissue fixation device within the bone tunnel to secure the graft therein. Rather, Dreyfuss is directed to a suture anchor. The suture anchor is driven into hard tissue and a suture is subsequently threaded around an exposed loop. Nowhere does Dreyfuss suggest fixing a tissue graft by placing the graft into a bone tunnel and securing the graft by inserting a tissue fixation device into the bone tunnel. Similarly, Gogolewski teaches a fixation pin but does not suggest using the fixation pin according to

the claimed method. In particular, Gogolewski's fixation pin is not used to fix a tissue graft within a bone tunnel. Sasso also lacks any suggestion of fixing a tissue graft within a bone tunnel. Instead, Sasso is directed to bone anchors or bone screws that can be implanted in a vertebral body to connect upper and lower portions of the vertebral body. (See Response filed on May 4, 2006, on page 5, paragraph 2 to page 6, paragraph 2).

Further, as previously explained in detail by Applicant, a plain reading of the body of claim 25 demonstrates that the claim does indeed positively recite the limitation of inserting a tissue graft into a bone tunnel. Claim 25 plainly recites the steps of "positioning a portion of the tissue graft within the bone tunnel" and "inserting the tissue fixation device within the bone tunnel to secure the tissue graft therein." (See also Response to Final Office Action, filed September 29, 2006, page 2, paragraph 3 to page 3). There is thus no basis for the Examiner's statement that the claimed method does not positively recite positioning a tissue graft in a bone tunnel and securing the tissue graft therein with a tissue fixation device.

These limitations are entirely absent from the teachings of the cited prior art, and the Examiner must give weight to these limitations.

Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness, and claim 25 distinguishes over Dreyfuss, Gogolewski and Sasso, taken alone or in combination. Claims 26-30 are allowable at least because they depend from claim 25.

Independent Claim 1

Claim 1 is directed to a bioimplantable tissue fixation device formed from a bioresorbable material. The Examiner argues that Dreyfuss teaches a tissue fixation device as recited in claim 1, except for the use of a bioresorbable material. The Examiner relies on Gogolewski to teach a fixation device formed from a bioresorbable material. In addition, the Examiner contends that "if one of ordinary skill in the art wanted to allow the suture anchor to remain *permanently* in the body, yet eliminate the risk of causing harm to tissue, the suture anchor could be made of a bioresorbable material," and that it is "well known in the surgical fastener art to form a fastener of a bioresorbable

material to prevent a surgeon from having to operate on a patient and remove the fastener after the healing process is completed.” (Final Office Action dated July 25, 2006, pg. 4; emphasis added).

This rejection fails to establish a *prima facie* case of obviousness. In particular, the Examiner provides no suggestion or motivation to modify the suture anchor of Dreyfuss with the polymers of Gogolewski to provide a fixation device that degrades in the body over time.

As previously discussed at length by Applicant, the Examiner’s reasoning ignores the fact that Dreyfuss’ inventive concept is specifically directed *against* the use of bioresorbable or biodegradable materials for its suture anchors. (See Response to Final Office Action, filed May 4, 2006, page 3, paragraph 1 to page 4, last paragraph).

Dreyfuss specifically teaches the use of *non*-bioresorbable materials, such as metals, as a way to overcome what it alleges to be drawbacks of biodegradable suture anchors. Thus, a person of ordinary skill in the art would have no motivation to modify the suture anchor of Dreyfuss such that is formed of a bioresorbable material because Dreyfuss specifically states that its device is to remain permanently in the body. There is no basis to modify Dreyfuss as proposed by the Examiner because to do so would be contrary to the teachings of Dreyfuss.

Further, the Examiner’s additional contentions provide no support for the suggested modification. At the outset, the Examiner’s statement is contradictory because if something were intended to remain in the body permanently it clearly would *not* be made of a bioresorbable material.

Moreover, even if one were to form the suture anchor of Dreyfuss from the bioresorbable material of Gogolewski, the resulting suture anchor would likely fail as a tissue fixation device. Any suture attaching tissue to a bone via the suture anchor would become unsecured once the suture anchor dissolved, leading to detachment of the tissue from bone. Applicant refers the review panel to the arguments raised in the Response to Final Office Action, filed September 29, 2006, on page 5, paragraphs 3-4. Therefore, the modification suggested by the Examiner would render the suture anchor of Dreyfuss unsatisfactory for its intended purpose of effectively securing sutures and preventing suture detachment. (See Dreyfuss, page 1, paragraph 14). As set forth in the Manual of

Patent Examining Procedure ("MPEP"), there is no suggestion or motivation to make a proposed modification if proposed modification renders the prior art unsatisfactory for its intended purpose. (MPEP § 2143.01 (V); *see also In re Gordon*, 221 USPQ 1125 (Fed. Cir. 1984)).


Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness, and thus, claim 1 distinguishes over the cited prior art, taken alone or in combination. Claims 2-24 are allowable at least because they depend from claim 1.

CONCLUSION

In summary, in view of the above remarks, Applicant submits that all claims are in condition for allowance, and allowance thereof is respectfully requested.

Dated: November 22, 2006

Respectfully submitted,

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PENDING CLAIMS

1. (Original) A bioimplantable tissue fixation device, comprising:
 - an elongate body formed of a biocompatible, bioresorbable material and having an outer surface, a proximal end, a distal end and a longitudinal axis extending therethrough;
 - an internal cavity extending into the body from an opening in the proximal end of the body, the internal cavity terminating proximal to the distal end; and
 - at least one opening formed in the outer surface of the body, each of the at least one openings being in fluid communication with the internal cavity such that the internal cavity is able to accept a treatment material for delivery external to the outer surface of the body through the at least one opening.
2. (Original) The fixation device of claim 1, wherein the elongate body is a pin adapted to secure bone and/or soft tissue graft.
3. (Original) The fixation device of claim 2, wherein the elongate body is constructed of polymers or copolymers formed from monomers selected from the group consisting of lactide; glycolide; ϵ -caprolactone; hydroxybuterate; hydroxyvalerate; 1,4-dioxepan-2-one; 1,5,8,12-tetraoxacyclotetradecane-7,14-dione; 1,5-dioxepan-2-one; 6,6-dimethyl-1,4-dioxan-2-one; 2,5-diketomorpholine; p-dioxanone (1,4-dioxan-2-one); trimethylene carbonate (1,3-dioxan-2-one); alkyl derivatives of trimethylene carbonate; δ -valerolactone; β -butyrolactone; γ -butyrolactone, ϵ -decalactone; pivalolactone; α,α -diethylpropiolactone; ethylene carbonate; ethylene oxalate; 3-methyl-1,4-dioxane-2,5-dione; 3,3-diethyl-1,4-dioxan-2,5-dione; and 6,8-dioxabicyclooctane-7-one.
4. (Original) The fixation device of claim 1, wherein the elongate body is formed of a polymer or copolymer selected from the group consisting of polylactic acid, aliphatic polyesters, poly(amino acids), poly(propylene fumarate), copoly(ether-esters), polyalkylene oxalates, polyamides, tyrosine-derived polycarbonates, poly(iminocarbonates), polyorthoesters, polyoxaesters, polyamidoesters, polyoxaesters containing amine groups, poly(anhydrides), polyphosphazenes, polyurethanes, poly(ether urethanes), poly(ester urethane), biosynthetic polymers and combinations thereof.

5. (Original) The fixation device of claim 2, wherein the elongate body has a length in the range of about 15 mm to 65 mm.
6. (Original) The fixation device of claim 1, wherein at least a portion of the outer surface of the elongate body includes surface features for holding the elongate body in position after it has been implanted.
7. (Original) The fixation device of claim 6, wherein the surface features are selected from the group consisting of roughened regions, threads, barbs, hooks, and combinations thereof.
8. (Original) The fixation device of claim 1, wherein the outer surface of the elongate body is smooth.
9. (Original) The fixation device of claim 1, wherein the outer surface of the elongate body is porous and the at least one opening formed in the outer surface results from a pore matrix extending between the internal cavity and the outer surface.
10. (Original) The fixation device of claim 1, wherein the at least one opening communicates with the internal cavity through at least one passageway.
11. (Original) The fixation device of claim 10, wherein the outer surface is non-porous.
12. (Original) The fixation device of claim 2, wherein the diameter of the pin is in the range of about 1 mm to 10 mm.
13. (Original) The fixation device of claim 2, wherein the resorption profile of the pin is in the range of about 12 to 60 weeks.
14. (Original) The fixation device of claim 1, wherein the diameter of the internal cavity is in the range of about 0.5 mm to 5 mm.
15. (Original) The fixation device of claim 9, wherein the pores have an average pore diameter in the range of about 0.01 mm to 5 mm.

16. (Original) The fixation device of claim 1, wherein the treatment material is a biologically active material.

17. (Original) The fixation device of claim 16, wherein the biologically active material is selected from the group consisting of tissue fragments, growth factors, proteins, analgesics, antibodies, enzymes, cytokines, glycosaminoglycans, viruses, virus particles, nucleic acids, peptides, isolated cells, platelets, and combinations thereof.

18. (Original) The fixation device of claim 1, wherein the treatment material is an adhesive agent.

19. (Original) The fixation device of claim 18, wherein the adhesive agent comprises an anchoring agent selected from the group consisting of hyaluronic acid, fibrin glue, fibrin clot, collagen gel, gelatin-resorcin-formalin adhesive, mussel-based adhesive, dihydroxyphenylalanine (DOPA) based adhesive, chitosan, transglutaminase, poly(amino acid)-based adhesive, cellulose-based adhesive, synthetic acrylate-based adhesives, platelet rich plasma (PRP), Matrigel, Monostearoyl Glycerol co-Succinate (MGSA), Monostearoyl Glycerol co-Succinate/polyethylene glycol (MGSA/PEG) copolymers, laminin, elastin, proteoglycans and combinations thereof.

20. (Original) The fixation device of claim 18, wherein the adhesive agent comprises a chemical cross-linking agent selected from the group consisting of divinyl sulfone (DVS), polyethylene glycon divinyl sulfone (VS-PEG-VS), hydroxyethyl methacrylate divinyl sulfone (HEMA-DIS-HEMA), formaldehyde, glutaraldehyde, aldehydes, isocyanates, alkyl and aryl halides, imidoesters, N-substituted maleimides, acylating compounds, carbodiimide, hydroxychloride, N-hydroxysuccinimide, light, pH, temperature, and combinations thereof.

21. (Original) The fixation device of claim 10, wherein the at least one opening formed in the outer surface of the body includes a number of openings in the range of about 5 to 25.

22. (Original) The fixation device of claim 10, wherein the diameter of the at least one opening is in the range of about 0.5 mm to 1.5 mm.

23. (Original) The fixation device of claim 1, wherein the elongate body has a substantially cylindrical shape.
24. (Original) The fixation device of claim 1, wherein the distal end of the elongate body tapers to a point.
25. (Original) A method for attaching a tissue graft to bone, comprising:
 forming a bone tunnel into bone;
 providing a tissue fixation device in the form of an elongate member having a longitudinally oriented channel formed therein that extends from an opening in a proximal end thereof, the tissue fixation device having at least one opening formed in a sidewall thereof that is in fluid communication with the channel;
 positioning a portion of the tissue graft within the bone tunnel;
 inserting the tissue fixation device within the bone tunnel to secure the tissue graft therein;
and
 injecting a treatment material into the channel of the tissue fixation device to enable the material to be secreted through the at least one opening to a region external to the sidewall of the tissue fixation device.
26. (Original) The method of claim 25, wherein the treatment material is a biologically active material.
27. (Original) The method of claim 26, wherein the biologically active material is selected from the group consisting of tissue fragments, growth factors, proteins, analgesics, antibodies, enzymes, cytokines, glycosaminoglycans, viruses, virus particles, nucleic acids, peptides, isolated cells, platelets, and combinations thereof..
28. (Original) The method of claim 25, wherein the treatment material is an adhesive agent.
29. (Original) The method of claim 28, wherein the adhesive agent comprises an anchoring agent selected from the group consisting of hyaluronic acid, fibrin glue, fibrin clot, collagen gel, gelatin-resorcin-formalin adhesive, mussel-based adhesive, dihydroxyphenylalanine (DOPA) based

adhesive, chitosan, transglutaminase, poly(amino acid)-based adhesive, cellulose-based adhesive, polysaccharide-based adhesive, synthetic acrylate-based adhesive, polyurethane-based adhesive, platelet rich plasma (PRP), platelet poor plasma (PPP), Matrigel, Monostearoyl Glycerol co-Succinate (MGSA), Monostearoyl Glycerol co-Succinate/polyethylene glycol (MGSA/PEG) copolymers, laminin, elastin, proteoglycans, and combinations thereof.

30. (Original) The method of claim 28, wherein the adhesive agent comprises a cross-linking agent selected from the group consisting of divinyl sulfone (DVS), polyethylene glycon divinyl sulfone (VS-PEG-VS), hydroxyethyl methacrylate divinyl sulfone (HEMA-DIS-HEMA), formaldehyde, glutaraldehyde, aldehydes, isocyanates, alkyl and aryl halides, imidoesters, N-substituted maleimides, acylating compounds, carbodiimide, hydroxychloride, N-hydroxysuccinimide, light, pH, temperature, and combinations thereof.

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